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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
AFREMOVA, VERA	

ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
10/21/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/562,734	NORDLUND ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/29/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of the Group I in the reply filed on 8/06/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)) and, therefore, made final.

Claims 16 and 17 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected claims, there being no allowable generic or linking claim.

Claims 1-15 are under examination in the instant office action.

Specification

The disclosure is objected to because of the following informalities:

Section with description of figures (Page 18) is missing the title "Brief Description of the Several Views of the Drawing(s)".

Appropriate correction is required.

Claim Objections

Claims 5-15 are objected to under 37 CFR 1.75(c) as being in improper form of multiple dependent claims. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, step (c) appears to miss word "protein" before the phrase "is not detected on the basis of its own enzymatic activity". Claims 5-15 are presented in improper form of multiple dependent claims and, thus, the relationship of structural elements as intended is uncertain. The concept of target proteins fused to tags that are detected by enzymatic reaction (claim 8) in the step (c) of claims 1-8 that is not based on enzymatic reaction are particularly uncertain. It is unclear what is and what is not detected by enzymatic reaction.

Claim 11 is rendered indefinite by reciting several "colonies" or "said colonies" in the method of claim 1 reciting one colony or cells originating from single colony. There is insufficient antecedent basis for this limitation in the claim. The concept of colony transfer is also uncertain as claimed. Claim 11 is also uncertain about timing of colony transfer. In alternative, claim 12 would be redundant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 4-15 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,506,121 (Skerra et al).

Claims are directed to a method of identifying a cell colony which expresses a soluble target protein wherein the method comprises steps of (a) subjecting said cell colony to conditions which are capable of causing lysis thereof; (b) filtering the lysate of step (a) through a filter

having pores which allow only soluble proteins to pass through the filter; and (c) detecting target protein which has passed through the filter, wherein the target is not detected on the basis of its own enzymatic activity. Some claims are further drawn to the lysis being a native lysis that is carried out by using a lysis buffer. Some claims are further drawn to the target protein that is fused to a protein or polypeptide tag including His tag. Some claims are further drawn to identifying or detecting soluble proteins in the filtrate using antibodies and/or fusion tags including tag acting as substrate for enzymatic detection. Some claims are further drawn to the use of filter with pore size between 0.1 and 1.5 μm. Some claims are further drawn to transfer of colonies from growth media to filter before lysis. Some claims are further drawn to the filtration step (b) that includes application of a generic force to the filter carrying the colonies.

US 5,506,121 (Skerra et al) discloses a "filter sandwich test" in a method for identifying a cell colony which expresses a soluble target protein (see entire document including example 1 at col. 6-7). The disclosed test method comprises steps of growing cell colonies on a first filter or on a first nitrocellulose filter membrane and transferring the first filter on top of the second filter that is coated with lysozyme and antibody, thereby, (a) subjecting cell colonies (including single separated colonies) to conditions which are capable of causing lysis of cell colonies present on the first upper filter ; (b) filtering the lysate of step (a) through the first filter having pores which allow soluble proteins to pass or to diffuse through the filter; and (c) detecting target protein which has passed through the filter, wherein the target protein is detected with antibody but not on the basis of its own enzymatic activity. The disclosed filtration step includes application of a generic gravitational force from top filter to the bottom capture filter in the "filter sandwich test". The cited method encompasses detection of target protein(s) that are fused to a protein or

polypeptide tag including His (see abstract, for example). The cited method encompasses identifying or detecting soluble proteins in the filtrate using antibodies (see col.7, line 3) and/or fusion tags including tag acting as substrate for enzymatic detection (see col.7, line 23). The cited method encompasses the use of nitrocellulose filter membrane that is a filter having pore size within the claimed ranges in view of applicant's disclosure, for example: see instant specification page 10, line 9 or fig. 2. The cited method encompasses transfer of colonies from a growth media to a lysis filter before subjecting to lysis and further capturing the filtrate on solid support of the second "capture" filter .

Thus, the cited method comprises identical active steps and identical structural elements as required by the claimed method. Therefore, the cited patent anticipates the claimed invention.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Knaust et al. (IDS reference; Analytical Biochemistry. 2001, 297:79-85).

Claims are directed to a method of identifying a cell colony which expresses a soluble target protein wherein the method comprises steps of (a) subjecting said cell colony to conditions which are capable of causing lysis thereof; (b) filtering the lysate of step (a) through a filter having pores which allow only soluble proteins to pass through the filter; and (c) detecting target protein which has passed through the filter, wherein the target is not detected on the basis of its own enzymatic activity. Some claims are further drawn to the lysis being a native lysis that is carried out by using a lysis buffer or by freeze thawing colonies. Some claims are further drawn to the target protein that is fused to a protein or polypeptide tag including His tag. Some claims are further drawn to identifying or detecting soluble proteins in the filtrate using

antibodies and/or fusion tags including tag acting as substrate for enzymatic detection. Some claims are further drawn to the use of filter with pore size between 0.1 and 1.5 μm. Some claims are further drawn to transfer of colonies from growth media to filter before lysis. Some claims are further drawn to the filtration step (b) that includes application of a generic force to the filter carrying the colonies.

The reference by Knaust et al. teaches a method of identifying a cell colony which expresses a soluble target protein wherein the method comprises steps of (a) subjecting cell originating from a single cell colony to conditions which are capable of causing lysis; (b) filtering the lysate of step (a) through a filter having pores which allow only soluble proteins to pass through the filter; and (c) detecting target protein which has passed through the with anti-RGS-His antibody (see entire document including abstract and figure 2). The lysis is carried out by using a lysis buffer and/or by freeze thawing (figure 2). The filter appears to have same pore size at least for the reason of filtration and detection same soluble proteins as intended for the claimed method. The cell colonies or cell mass is transferred from growth media to lysis filter before lysis as encompassed by the instant claims. The filtration step includes application of a force including gravitation and vacuum manifold (figure 2). Thus, the cited method comprises identical active steps and identical structural elements as required by the claimed method. Therefore, the cited reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,506,121 (Skerra et al) and Knaust et al. (IDS reference; Analytical Biochemistry. 2001, 297:79-85).

Claims as above.

The cited documents US 5,506,121 (Skerra et al) and Knaust et al. are relied upon as explained above for the teaching of the methods of identifying cell colonies expressing soluble target proteins wherein the method comprises steps of (a) subjecting cell colony(ies) to conditions which are capable of causing lysis thereof; (b) filtering the lysate of step (a) through a filter having pores which allow only soluble proteins to pass through the filter; and (c) detecting target protein which has passed through the filter, wherein the target is not detected on the basis of its own enzymatic activity. The soluble target proteins are detected with antibodies as disclosed by the cited references. The cited references disclose detection of soluble proteins having same generic tags as encompassed by the claims including His tag. The cell lysis in the method of US 5,506,121 (Skerra et al) is caused by lysozyme or buffer. The cell lysis in the method of Knaust et al. is caused by both lysing buffer and/or freeze thawing.

Thus, the cited documents taken as a whole teach and/or suggest all claimed limitations.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to apply either lysing buffer or freeze thawing cells in order to lyse cell and to liberate soluble proteins with a reasonable expectation of success in filtrating and detecting soluble proteins in the method of identifying cell colonies expressing soluble target

proteins as taught and/or suggested by the cited references. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

October 9, 2008

VERA AFREMOVA

PRIMARY EXAMINER

/Vera Afremova/
Primary Examiner, Art Unit 1657